PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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Bearb.: EF:
Frist:
Abfrage:

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)* 17.01.2006

Applicant's or agent's file reference
C5147PWO-R/Bi

IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/012618	08.11.2004	07.11.2003

Applicant
CORAL LICENSING INTERNATIONAL LTD. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
C5147PWO-R/Bi		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/012618	08.11.2004	07.11.2003

International Patent Classification (IPC) or both national classification and IPC

A61N1/36, A61B5/0456, A61B5/0245

Applicant

CORAL LICENSING INTERNATIONAL LTD. et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 9 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07.09.2005	17.01.2006

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP2004/012618

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-55 as originally filed

Claims, Numbers

1-17 received on 07.09.2005 with letter of 06.09.2005

Drawings, Sheets

1/9-9/9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 11-17

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 11-17

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-10
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-10
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations

   see separate sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT - SEPARATE SHEET

International application No. PCT/EP2004/012618

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

No search has been carried out for the subject-matter of claims 11-17 (original claims 21-27), since these claims relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Indeed claims 11-17 pertain to a method for providing electrotherapy pulses to the human body and consequently concern a method of treatment of the human body by therapy. Consequently, no opinion will be formulated with respect to these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:
   D1: WO 01/13990 A (CARDIOREST LTD) 1 March 2001
   D2: EP-A-0 847 776 (BAVARIA PATENTE UND LIZENZEN VERWERTUNGSGESELLSCHAFT MBH) 17 June 1998
   D3: WO 98/05379 A (CHOU, ONES, C) 12 February 1998

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-10 is not new in the sense of Article 33(2) PCT.

2.1 Claims 1-2

As acknowledged by the applicant in the description of the present application, document D1 (from the same inventors) discloses an electrotherapy apparatus according to the preamble of claim 1 (everything before feature a) of claim 1).
However, D1 also discloses the remaining features of claim 1, i.e. feature a) (see p. 24, last para. - p. 25, last para. and fig. 2A, 5) and features b) to f) (see p. 41, third para. - p. 42, third para.).
D1 also discloses the feature of a measurement window configured to avoid so-called

interferences (i.e. disturbance of the R-wave detection by the muscle stimulation pulses) (see p. 59, third para. - p. 61, second para.) and the feature of an adaptive impulse delay (see p. 61, third para. - p. 64, last line). Accordingly, the subject-matter of **claims 1-2** is not new (Article 33 (2) PCT).

2.2 Claims 7-8

As seen above in point 2.1, document D1 (from the same inventors) discloses an electrotherapy apparatus according to the preamble of claim 7. Further, (everything before feature a) of claim 1). D1 also discloses a plurality of output channels for applying electrical stimulation to a plurality of active electrodes (see p. 32, third para. - p. 33, third para.). As can be seen from fig. 2A, two pairs each comprising two electrodes are provided in D1, so that D1 discloses a plurality of channel groups, each channel comprising the same number of channels.
Further, in D1 (see p. 33, first to fourth para.), stimulation signals are applied to the electrodes in sequence, hence each channel group is provided with a respective different time delay, i.e. one group is provided with a predetermined time delay and the other group with the same time delay plus a time offset. Therefore, the subject-matter of **claims 7-8** is also not new (Article 33 (2) PCT).

It is to be noted that the subject-matter of these claims also lacks an inventive step (Article 33 (3) PCT) in view of D2 (see in particular col. 3, l. 15-53 and col. 6, l. 47-56), where a similar apparatus applies offset delays to a plurality of stimulation channels.

2.3 D1 also shows features of dependent claims 3-6, 9-10.

- In D1 (see p. 41, 2nd para.), stimulation is inhibited in case of arrhythmia or if the heart rate is outside the allowed range. Hence, **claim 3** is also anticipated by D1 (Article 33 (2) PCT).

- The subject-matter of **claims 4-5** lacks also novelty, since D1 shows averaging of measured values (p. 63, fourth para.)

- The subject-matter of **claim 6** lacks also novelty, since D1 also discusses a plurality of output channels for applying electrical stimulation to a plurality of active electrodes

(see p. 32, third para. - p. 33, third para.).

- Moreover, in D1, a non-electric heart rate sensor is used in the form of a non-invasive aortic pressure measurement device (blood pressure measuring cuff 131 in fig. 5). Furthermore, the non-electric heart rate sensor can be used in addition to the ECG sensor or it can be used alone (see p. 46, first para.). Consequently, **claims 9-10** are also not new (Article 33 (2) PCT).

It is to be noted that the obvious alternative of an acoustic heart rate sensor is shown in D3 (p. 6, l. 24 - p. 7, l. 13), so that a restriction to this feature is not regarded as inventive (Article 33 (3) PCT).

3. It is further to be noted that features a) to n) of claim 1 merely refers to the automated process described in D1, so that no inventive step can be recognised in the fact of implementing the "steps" a) to n) in a processor device (Article 33 (3) PCT).

Patent Claims

1. Electrotherapy apparatus comprising a sensor for detecting periodically recurring signal peaks, for example the R-R peaks of an electrocardiogram of a person, a processor for deriving from said periodically recurring signal peaks a time delay corresponding to approximately the end of the T-wave, a trigger system or a circuit initiated by an output signal of said processor or embodied within said processor for applying electrical stimulations to one or more active electrodes provided on the said person at a time related to the end of said time delay, the processor being adapted:

   a) to make a determination for successive pairs of signal peaks of a value corresponding to the time between said successive pairs of signal peaks and thus to the said person's heart rate,

   b) to compare said value with maximum and minimum permissible technical limits permitted by the apparatus and/or

   c) to compare said value with maximum and minimum permissible selected limits,

   d) to determine whether each said value exceeds a preceding value or a preceding value averaged over a plurality of heart beats by more than a defined amount,

   e) to determine whether each said value is less than a preceding value or a preceding value averaged over a plurality of heart beats by more than a defined amount,

f) to trigger said trigger system or circuit only when the comparisons b) and/or c) are favourable and the determinations d) and e) show that the said value does not exceed the preceding value or the preceding average value by more than the defined amount and is not less than the preceding value or the preceding value by more than the defined amount,

g) to close a measurement window for said sensor once a determination is made that the comparisons b) and/or c) are favourable and that the determinations d) and e) show that the said value does not exceed the preceding value or the preceding average value by more than the defined amount and is not less than the preceding value or the preceding average value by more than the defined amount, said measurement window being closed prior to triggering said trigger system,

h) to calculate in addition to said time delay a maximum stimulation length,

i) to check that the derived value of said time delay is greater than or equal to a delay time equivalent to a trigger delay plus a calculation delay, said trigger delay being the delay between initiation of a trigger signal delivered by said sensor corresponding to the detection of a first signal peak and the time this signal reaches the processor and the calculation delay being the time required by the processor to derive the delay,

j) to check that the derived time delay is less than or equal to said maximum stimulation length and to revise said derived time delay if necessary so that it fulfils the two conditions de-

rived time delay greater than or equal to the trigger delay plus the calculation delay and derived time delay less than or equal to the maximum stimulation length,

k) to calculate a maximum duration equal to the maximum stimulation length minus the time delay,

l) to calculate a duration of said electrical stimulation and a maximum duration value equal to said maximum stimulation length minus said derived time delay and to check whether said calculated duration is less than or equal to said maximum duration and if not to adapt it so that it is less than or equal to said maximum duration,

m) to calculate an open measurement window time equal to said derived time delay, or said adapted delay, if said delay has been adapted, plus said duration or said adapted duration, if said duration has been adapted, plus a safety margin, and

n) to send an output signal to said trigger system during said measurement window and open said measurement window at the calculated time permitting the recognition of the detection of a further peak of said electrocardiogram by said sensor.

2. Electrotherapy apparatus in accordance with claim 1, characterized in that
said processor is adapted to repeat the sequence of steps based on the new R-R value.

3. Electrotherapy apparatus in accordance with claim 2,

characterized in that
if a further signal peak is not detected after opening of said measurement window within an expected time calculated by said processor based on a preceding value or a preceding average value, no trigger signal is transmitted and transmission of a trigger signal and thus stimulation is inhibited until further signal peaks are detected within expected limits.

4. Electrotherapy apparatus in accordance with any one of the preceding claims,
characterized in that
instead of using a value of the preceding time between signal peaks as said value an average is formed from a plurality of past values.

5. Electrotherapy apparatus in accordance with claim 4,
characterized in that
the processor is adapted to include in said plurality of past values only those values which lie within a range less than the preceding measured value plus a predefined positive deviation and more than a value corresponding to the preceding measured value less a predefined deviation.

6. Electrotherapy apparatus in accordance with any one of the preceding claims,
characterized in that
the apparatus has a plurality of channels for applying electrical stimulations to one or more active electrodes provided on the said person and in that for each said channel a respective offset value is added to said delay.

7. Electrotherapy apparatus comprising a sensor for detecting periodically recurring signal peaks, for example the R-R peaks of an electrocardiogram of a person, a processor for deriving from said periodically recurring signal peaks a time delay corresponding to approximately the end of the next T-wave, a trigger system or circuit initiated by an output signal of said processor or embodied within said processor for applying electrical stimulations to one or more active electrodes provided on the said person at a time related to the end of said time delay, wherein the apparatus has a plurality of output channels for applying electrical stimulations to said one or more active electrodes provided on the said person,
characterized in that a plurality (Y) of channel groups (A, B; A, B, C) is provided, each channel group (A, B; A, B, C) comprising a plurality of channels,
in that each channel group (A, B; A, B, C) has the same number of channels (Ch.1, Ch. 2, Ch. 3, Ch.4 (Group A);
Ch. 5, Ch. 6, Ch. 7, Ch. 8 (Group B); Ch. 9, Ch. 10, Ch. 11, Ch. 12 (Group C)),
in that means are provided for providing each channel group (A, B; A, B, C) with a respective time delay generally different from time delays associated with other channel groups.

8. Electrotherapy apparatus in accordance with claim 7,
characterized in that
the processor is adapted to provide a said time delay for one group of channels (A) and to add a respective time offset to said time delay for each further channel group (B; B, C).

9. Electrotherapy apparatus in accordance with any one of the preceding claims 7 or 8,

characterized in that
said sensor is a non-electric sensor, or a non-electric sensor used in addition to an electrocardiograph.

10. Electrotherapy apparatus in accordance with claim 9, characterized in that
said non-electric sensor is selected from the group comprising a non-invasive, aortic pressure measurement device, an invasive aortic pressure measurement device and a noise detection device adapted to detect the closing of the heart valves.

11. A method of treating a person or a mammal using electrotherapy apparatus in accordance with claim 7 or claim 8, characterized in that
each output channel provides a respective time delay generally different from a time delay associated with any other output channel and that the output channels are either all connected to a common electrode affecting a particular muscle or muscle group or are connected to respective electrodes each affecting a respective muscle or group of muscles.

12. A method of treating a person or a mammal using electrotherapy apparatus in accordance with any one of claims 7 to 10, characterized in that
each channel group of output channels is associated with a group of muscles in general proximity to one another on a body of said person or mammal, with the group of muscles associated with each group of output channels being the same group of muscles for each group of output channels, and in that the stimulation signals transmitted via each group of output channels is offset time-wise in

relation to stimulation signals transmitted by any other group of output channels.

13. A method of treating a person or a mammal using electrotherapy apparatus in accordance with any one of claims 7 to 10, characterized in that
each channel group of output channels is associated with a respective group of muscles in general proximity to one another on a body of said person or mammal, in that the group of muscles associated with one group of output channels differs from a group of muscles associated with any other group of output channels, and in that the stimulation signals transmitted from each group of output channels to the respectively associated group of muscles are triggered at the same time for each group of channels.

14. A method of treating a person or a mammal using electrotherapy apparatus in accordance with any one of claims 7 to 10, characterized in that
each channel group of output channels is associated with a respective group of muscles in general proximity to one another on a body of said person or mammal, in that the group of muscles associated with one group of output channels differs from a group of muscles associated with any other group of output channels, and in that the stimulation signals transmitted from each group of output channels to the respectively associated group of muscles are triggered at different times for each group of channels.

15. A method in accordance with claim 14, characterized in that

the groups of muscles respectively associated with each group of channels are disposed on a body of said person or mammal such that a group of muscles closer to the heart and associated with one group of channels is stimulated later than a group of muscles disposed further from the heart and associated with another group of channels.

16. A method in accordance with claim 14,
characterized in that
the groups of muscles respectively associated with each group of channels are disposed on a body of said person or mammal such that a group of muscles further from the heart and associated with one group of channels is stimulated later than a group of muscles disposed closer to the heart and associated with another group of channels.

17. A method in accordance with claim 15 or claim 16,
characterized in that
the first group of channels comprises four channels associated with four active electrodes, namely first and second active electrodes disposed over the lateralis muscles at the left and right front sides of the human body, and third and fourth active electrodes disposed over the glutea muscles disposed at the rear of a person's body to the left and right thereof, with passive electrodes being disposed over the infra inguinalis muscles provided at the left and right at the front of the human body, in that the second group of channels comprises four channels associated with four active electrodes, namely first and second active electrodes disposed over the femoralis medialis muscles on the left and right thighs at the front of the human body, and third and fourth active electrodes provided over

the sulcus glutealis muscles beneath the left and right buttocks, with passive electrodes being provided above the supragenus muscles above the knees and in that

the third group of channels comprises four channels associated with four active electrodes, namely first and second active electrodes provided above the medialis muscles below the left and right knees, and third and fourth active electrodes being provided over the lateralis muscles on the left and right calves, with passive electrodes being provided above the doralis pedis muscles on the left and right feet.